

Title:

**Dynamic intraligamentary stabilization versus conventional ACL reconstruction:
A matched study on return to work**

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ABSTRACT

Purpose: The dynamic intraligamentary stabilization (DIS) technique is based on a different treatment approach than ACL reconstruction in that it intends to promote self-healing of the ligament. It is only recommended for acute injuries (<21 days). The purpose of the present study was to compare DIS and ACLR with respect to the extent of work incapacity, revision rates, secondary arthroscopies, and treatment costs during recovery

Methods: The study was a post-hoc analysis of prospectively collected data in the Swiss National Accident Insurance Fund (SUVA) database. All registered DIS cases treated until 31 December 2012 were included in the study. ACLR cases were matched to DIS cases using a propensity score approach and analysed in a follow-up period of 2 years after injury. Paired Student's T-test and the Chi-square test were used to compare the outcome measures.

Results: All 53 DIS patients were matched to an ACLR pair. The mean time period from injury to surgery was 14 days for DIS and 50 days for ACLR ($p < 0.001$). Overall work incapacity was 13% for DIS and 17% for ACLR resulting in a difference of nearly 1 month of absence from work ($p = 0.03$). The course of postoperative work incapacity was very similar between the groups, while the work incapacity prior to surgery lower in the DIS group. We found no difference in treatment costs, secondary arthroscopies and revision rates.

Conclusion: DIS patients benefited from nearly one month shorter absence from work than ACLR patients. This difference is likely related to the early surgical timing that is recommended for DIS. Since no differences were found between DIS and ACLR in terms of treatment costs, secondary arthroscopies and revision rates, the study supports the choice of DIS as an additional treatment option for acute ACL injuries. Further comparative studies are proposed to improve the evidence about optimal timing and best practice in ACL treatment.

INTRODUCTION

Rupture of the anterior cruciate ligament (ACL) of the knee is increasingly common, and the number of reconstruction surgeries performed annually in western countries is estimated between 34 and 44 per 1000000 people.^{1,2} Optimal management of ACL ruptures is still widely discussed, and unsatisfactory recovery of knee function in the short- and long-term is still frequently reported.³⁻⁵ Recently, dynamic intraligamentary stabilization (DIS) was reported as an alternative option for repair of acute ACL ruptures⁶, based on the hypothesis that the ruptured ACL possesses an inherent biological healing capacity⁷. In contrast to conventional arthroscopic ACL reconstruction (ACLR), the use of DIS is recommended to exploit the healing potential of the ligament⁶. Graft harvesting in DIS is not required. The technique relies on providing knee joint stability during ACL healing. Proponents of DIS see the advantage of this technique in the preservation of the still living ligament tissue and its sensory pathway to the neuromuscular system⁸ to enable faster and better treatment and injury recovery. However, no comparative evidence between DIS and ACLR exists so far. Recovery from ACL injury is frequently measured in terms of patient subjective evaluation or sports-related (dis)abilities.⁹ Currently, more attention is focussed on the health-economic impact of ACL injuries, in view of increasing health care expenses and limited resources^{10,11}. One of the most important aspects in the health care system is 'work capacity', which is a multifactorial concept that includes both economic and health-related perspectives^{12,13}.

The following study compares the post-injury recovery between DIS and ACLR by investigating work incapacity during an observation period of 2 years after the accident, treatment costs in the Swiss health care system, surgical interventions during follow-up (e.g. secondary arthroscopies) and revision rates.

MATERIALS AND METHODS

Study design

The study was a case-control matching analysis of prospectively collected data in the Swiss National Accident Insurance Fund (Schweizerische Unfallversicherungsanstalt, Suva) database. In Switzerland, all employees are legally required to be insured against accidents. Suva is a public sector social insurance, covering health care expenditures and compensation for work incapacity after accidents for 60% of the overall population in Switzerland. In the case of a reduced work capacity, employees receive 80% of their wages. The Suva database includes socio-demographic and administrative data, medical reports and accounting. The authors retrospectively compared records of patients that underwent either DIS surgery or ACLR surgery as a treatment for ACL injury. The cut-off date for 2 years of follow-up after the accident was 31 December 2014.

For this study, ethical approval and formal consent were not required, as the study used anonymous data from an administrative database.

DIS technique

The DIS technique is used for the same patient population as ACLR. The operative technique for DIS was previously described⁶. In brief, a monobloc screw with an integrated spring system (LigamysTM, Mathys Ltd, Bettlach, Switzerland) is fixed into the tibia. Then, a polyethylene cord is secured in the femur and guided to the tibia (Fig. 1). Before anchoring the cord in the screw-spring system, microfracturing is performed to allow stem cells to migrate into the joint and accelerate the healing process. Finally, the polyethylene cord is fixed with a predetermined tension of 50–80 N (depending on patient sex and weight). This ensures that the femur and the tibia cannot shift against each other during movements and provide continuous stability of the knee joint during the self-healing period. The two ligament stumps are not sutured together, but are kept in close proximity using the cord allowing the stumps to make loose contact and to grow together free from tensile load.

Study population

The inclusion criteria for this study were (i) coverage by Suva compulsory accident insurance (ii) primary traumatic ACL rupture in the years 2011 or 2012, and (iii) age between 18 and 55 years. For ACLR, an additional inclusion criterion was autograft transplants with a delay between the primary rupture and surgery of less than 360 days without initial conservative treatment. All registered cases had a 2-year follow-up. A total of 273 cases with DIS (n = 58) or ACLR (n = 215) met the inclusion criteria. The exclusion criteria were (iv) incomplete patient records (n = 9), (v) conservative treatment approach with delayed ACLR (n = 8), (vi) re-rupture of the ACL during follow-up (n = 7), and (vii) concomitant knee injuries (n = 35) such as knee dislocation (n = 4), reconstructed collateral ligament (n = 3), acute cartilage damage (n = 2), and others (n = 2). The selection resulted in 53 DIS and 185 ACLR cases eligible for matching.

Matching procedure

ACLR patients were matched to DIS patients n:1 on propensity score using criteria which represent key confounders of surgical outcomes^{14,15}: (i) age, (ii) sex, (iii) working category, (iv) date of ACL rupture and (v) time between rupture and surgery. The variables of the matching criteria were transformed to z-normalized values and the Euclidian distance between each DIS and ACLR case was calculated. The cases of both groups with the smallest Euclidian distance were matched until the scores indicated that further matching partners fit worse than partners that were already matched. The cut-off criterion for the matching procedure was reached when a total of 80 ACLR cases were matched to the 53 DIS cases. Twenty-one DIS cases had >1 ACLR partner that matched equally well. The final matching obtained was 1:1 for 32 DIS cases (32 ACLR), 2:1 for 17 DIS cases (34 ACLR), 3:1 for 2 DIS cases (6 ACLR), and 4:1 for 2 DIS cases (8 ACLR). Subsequently, ACLR cases with matching ratios >1:1 were proportionally down-weighted to build equal group sizes.

Patient characteristics

Patient characteristics included sex, age, physical work intensity and cause of the accident (leisure vs. work). Work intensity groups were created according to the required physical activity level¹⁶. In addition, data from the surgical intervention at baseline such as timing and treatment of concomitant (meniscal) injuries was recorded.

Outcome measures

Our primary outcome was post-injury work incapacity derived from accounting data on daily allowances paid after the accident. It was expressed as a percentage of pre-injury work incapacity. This concept included unemployment, change of employer and part-time employment. Relapses during follow-up were also taken into account.

The following secondary outcomes were assessed:

- Surgical interventions during follow-up (minor interventions, secondary arthroscopies, implant removal and revision ACL surgery).
- Total treatment costs, expressed as cumulative healthcare expenditures in Swiss francs. Costs included inpatient and outpatient treatment, physiotherapy, medication and medical aids.
- The effort of physiotherapeutic rehabilitation after hospitalisation, recorded as the number of invoiced physiotherapeutic sessions during follow up. The rehabilitation was guided by physical therapists according to standardized principles for ACL ruptures. These principles are the same in DIS and ACLR^{17,18}. In brief, for isolated ACL ruptures or ACL ruptures with partial resection of the meniscal lesions, immediate full weight bearing is generally allowed. For sutured meniscal lesions, additional brace wearing and partial weight bearing for four to six weeks after surgery is recommended.

Statistical analysis

Computation of statistics and statistical tests used the proportionally down-weighted ACLR cases with matching ratios >1:1. Descriptive statistics were expressed as mean \pm standard deviation (SD). The paired Student's t-test and the Chi-square test were used for analysis of differences between DIS and ACLR with a level of significance set to 0.05. All data preparation and statistical analyses were conducted using SAS software, Version 9.3 (SAS Institute Inc., Cary, NC, USA).

RESULTS

Patient characteristics and surgical intervention at baseline

Patient characteristics were similar between the groups (Table 1) with the exception of time to surgery. The difference in means between DIS (14 days) and ACLR (50 days) was 36 days ($p < 0.001$). In ACLR, 67% hamstring tendon grafts, 27% patellar tendon grafts, and 6% quadriceps tendon grafts were used. Two patients in each group experienced a rupture of the collateral ligament, which was treated conservatively. Despite the overall similar proportion of additional meniscal surgery, surgical technique varied significantly between groups. In 93% of the DIS cases, the meniscus lesion was sutured, while in 75% of ACLR mainly partial resection was performed (75%) ($p < 0.001$).

Work incapacity

Referring to the date of the accident, the curves of DIS and ACLR proceeded differently. Fig. 2 shows the different delays from injury to surgery and the larger temporal scattering of the surgery for ACLR. The curves of work incapacity after surgery were nearly identical for both groups (Fig. 3). The average work incapacity within the first year after injury was $23 \pm 4\%$ for DIS compared with $32 \pm 17\%$ for ACLR ($p < 0.001$). At the two-year follow-up it was $13 \pm 10\%$ for DIS and $17 \pm 10\%$ for ACLR ($p = 0.030$). This corresponded to 95 calendar days in DIS compared with 117 calendar days in ACLR, which were lost due to work incapacity during the first two years after injury. Thus, the work incapacity was lower in

the DIS group. No differences were seen for different work intensity between the two treatment groups. All patients returned to the level of pre-injury work capacity at the 2-year follow-up time point.

Surgical interventions during follow-up

Three cases (2 DIS, 1 ACLR) suffered from a major adverse event (infection) immediately after the index surgery. Arthroscopic surgery during follow-up was required in 19 cases (9 DIS, 10 ACLR) (Table 2). In four patients (2 DIS, 2 ACLR) more than one arthroscopic surgery was performed. Hardware removal was conducted significantly more often in DIS. Eight implant removals (7 DIS, 1 ACLR) were combined with arthroscopic surgery. There was no difference in the frequency of other surgical interventions required during follow-up between groups. Nine ACL revisions (5 DIS, 4 ACLR) were necessary due to traumatic re-injuries during sport activities and one (DIS) was due to chronic instability.

Treatment costs and rehabilitation

There was no statistically significant difference in total treatment costs per case between DIS (14'400 \pm 6'000 Swiss francs) and ACLR (13'700 \pm 4'300 Swiss francs) ($p = 0.50$). The mean number of physiotherapy rehabilitation sessions per patient was smaller in DIS (39 \pm 18 sessions) than in ACLR (47 \pm 24 sessions) ($p = 0.040$).

DISCUSSION

The main finding of this study was the significantly lower work incapacity in patients who underwent DIS compared with patients with ACLR. There were no between-groups differences in the proportion of secondary arthroscopies, treatment costs and revision rates. The clinical evaluation of a first case series of 278 DIS patients showed almost normal knee function, excellent satisfaction and a return to previous sports levels in most patients⁶. In this study, the focus was the work incapacity during post-injury recovery. Surprisingly, there are limited data on work incapacity as an outcome measure in ACL

surgery. Prior work has shown inferior clinical outcomes in patients receiving Workers' Compensations claims compared with patients without reimbursements^{19,20}. In Switzerland, all employees receive similar economic compensation after an accident. This ensures a certain comparability between individual patient data. The overall work incapacity (as a percentage of pre-injury work capacity) within the two years of follow-up was significantly lower after DIS compared with ACLR. The difference of 4% corresponds to nearly one month of presence at work. This is not a negligible difference, as it may have substantial economic consequences. Since no between-group differences were observed in the postoperative course of work incapacity, the timing of surgery may be responsible for the lower overall work incapacity in DIS. The timing of surgery remained different in the two groups, even though it was one of the matching criteria. In Switzerland, the time frame of 6 weeks or longer is generally recommended for ACLR, based on the long-held claim of Shelbourne et al.²¹, in order to avoid post-surgical stiffness. This delay also allows for better planning of elective surgery. On the other hand, DIS is recommended up to the first 21 days after injury to preserve the ligament. Even though surgical timing is still controversially discussed in the literature, a recent trend towards early surgery can be observed²². Several studies found early ACLR (<6–12 weeks post-injury) to be associated with equivalent^{9,14,23,24} or superior^{14,23,25} clinical results compared to late ACLR (>6–20 weeks) for various outcomes including active knee function^{14,23,25}, knee laxity^{9,14,23-25}, subjective knee evaluations^{9,14,23-25}, and sport activity level^{9,14,23,25}, in mid-²³⁻²⁵ and long-term^{9,14}. Reducing the time between injury and surgery also decreases the period of physiological inactivity of patients. When surgery is delayed and articular effusion resolved, the body perceives the surgery as a second trauma requiring another healing process. This may have a significant impact on short-term recovery.

In the current study, 93% of all DIS patients with meniscal lesions were sutured immediately. Only four cases (8%) had meniscal revision surgery. In ACLR, 75% of all meniscal lesions were partially resected. Although restrictive rehabilitation and initial partial weight-bearing for sutured meniscal lesions are recommended, the duration of rehabilitation and work incapacity was not longer in DIS than in ACLR patients. Moreover, the duration of physical therapy was significantly shorter (17%) in DIS. In the

literature, meniscal injury followed by an arthroscopic meniscectomy is described as the most important risk factor for the development of knee osteoarthritis when the ACL has been injured and already reconstructed²⁶. Compared with meniscectomy, meniscal repair offers significantly improved results regarding long-term arthritic changes, sports activity recovery and subjective scores^{27,28}. To create an environment for meniscal healing, performance of an immediate meniscal suture is of particular interest. A missed unstable meniscus, combined with knee instability, will destroy the meniscal tissue and consequently end in surgical removal²⁹. Anderson and Anderson³⁰ stated that an increasing severity of meniscal tears, revision of repair, and irreparable meniscal tears were all more commonly associated with delayed (>6 weeks) reconstruction. In a 6-year follow-up study, Tengrootenhuysen et al. [29] found early meniscal repairs completed ≤ 6 weeks after injury to have better results in terms of osteoarthritic changes and subjective scores than late repairs. Secondary minor and arthroscopic interventions have consistently been reported to be rare^{9,14,25,31}. Various studies found a greater incidence of meniscal lesions and subsequent meniscectomies in patients with a delayed surgery^{9,32-34}. However, the focus on DIS technique with its recommendation for acute injuries resulted in a shorter average time to surgery in both groups (7 weeks) compared with this study (5 months to 2 years). In DIS, the monobloc spring-screw used as the anchoring device has to withstand high tensile loads and is therefore bulkier than hardware used in ACLR. Although it can be left in situ after ACL healing, Henle et al.⁶ reported that up to half of patients requested implant removal without any clinical need. Our study mirrored this situation with a six times higher removal rate in DIS compared with ACLR. In ACLR, this procedure is generally very rare^{14,25}. However, monobloc removal in DIS is minimally invasive, carried out under local anesthesia, and does not affect the recovery process. The revision rates in both treatment groups were similar to these from two recently published systematic reviews on ACL reconstruction³⁵. For DIS, the rate was higher (11%) than for ACLR (7%), but this difference was not statistically significant. In a recent prospective study of 278 consecutive DIS cases, Henle et al.⁶ found a lower revision rate (4%), which may be due to inclusion of patients operated by a single surgical team.

Some limitations of the study deserve mention. The results of the study may only be generalizable within Switzerland. No functional or clinical scores and patient satisfaction between the two surgical procedures were studied, as these measures are not part of the Suva documentation. It was also difficult to find an appropriate control group. Patients receiving conservative (nonsurgical) treatment could not serve as a comparator in this study, as the database did not provide the necessary information about these cases. It was not possible to control for the surgery timing due to different philosophies for the two treatment approaches. In Switzerland, evidence-based recommendations are only available for the decision making process between conservative and surgical treatment options [1]. For surgical timing, standardized guidelines are offered only for DIS.

Our study is the first to compare DIS to ACLR. The multi-centric data collection was well standardized, based on a large national database. Future research should focus on comparative studies of DIS and ACLR, and clarify the differential benefits offered by each surgical procedure, and by early versus late timing of surgery. Further observational studies may help answer some open questions, especially in countries where early ACLR is currently performed. Ultimately, randomized controlled trials are the best design for studying the comparative efficacy of these surgical procedures.

Conclusion

DIS patients benefited from nearly one month shorter absence from work than ACLR patients. This difference is most likely related to the earlier surgery in DIS patients, as postoperative course of work incapacity was quite similar between the treatment groups. Since no differences were found in treatment costs, secondary arthroscopies and revision rates, our results support DIS as an additional treatment option for acute ACL injuries. Further comparative studies are proposed to improve the evidence about optimal timing and best practice in ACL treatment.

CONFLICT OF INTEREST STATEMENT

None.

273

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TABLES**Table 1**

Demographics and surgical intervention at baseline

	DIS (N = 53)	ACLR (N = 53)	p value
Patient characteristics			
Age (yr), mean \pm SD	30 \pm 8.5	31 \pm 7.6	0.40
Male sex, n	43 (81%)	43 (81%)	1.00
Low work intensity, n	29 (55%)	32 (60%)	0.74
High work intensity, n	24 (45%)	21 (40%)	0.31
Leisure injury, n	50 (94%)	49 (93%)	0.70
Surgical intervention at baseline			
Time rupture-surgery (d), mean \pm SD	14 \pm 12.8	50 \pm 27.3	<0.001
Total menisci surgery, n	28 (53%)	32 (60%)	0.47
Menisci fixation, n	26 (49%)	8 (15%)	<0.001
Menisci partial resection, n	2 (4%)	24 (45%)	<0.001

Table 2

Surgical interventions during follow-up

	DIS (N = 53)	ACLR (N = 53)	p value
Minor intervention			
Mobilization under anesthesia, n	4 (8%)	1 (2%)	0.17
Infiltration, n	2 (4%)	1 (2%)	0.56
Arthrocentesis, n	1 (2%)	1 (2%)	1.00
Secondary arthroscopy			
Menisci fixation, n	2 (4%)	0 (0%)	0.15
Menisci partial resection, n	2 (4%)	4 (8%)	0.90
Debridement (transplant/ligament), n	3 (6%)	2 (4%)	0.77
General joint lavage, n	5 (9%)	7 (13%)	0.70
Total cases with secondary arthroscopy, n	9 (17%)	10 (19%)	0.67
Implant removal			
Metal removal, n	19 (36%)	3 (6%)	<0.001
ACL revision			
Revision surgery, n	6 (11%)	4 (7%)	0.47

FIGURES

Figure 1

Schematic illustration of the dynamic intraligamentary stabilization (DIS) technique

Note: a monobloc screw with an integrated spring system is fixed into the tibia and a polyethylene cord is secured in the femur. The two cruciate ligament stumps are not sutured together but adapted to each other using the cord. The ruptured ends make loose contact and can grow together free from tensile load.

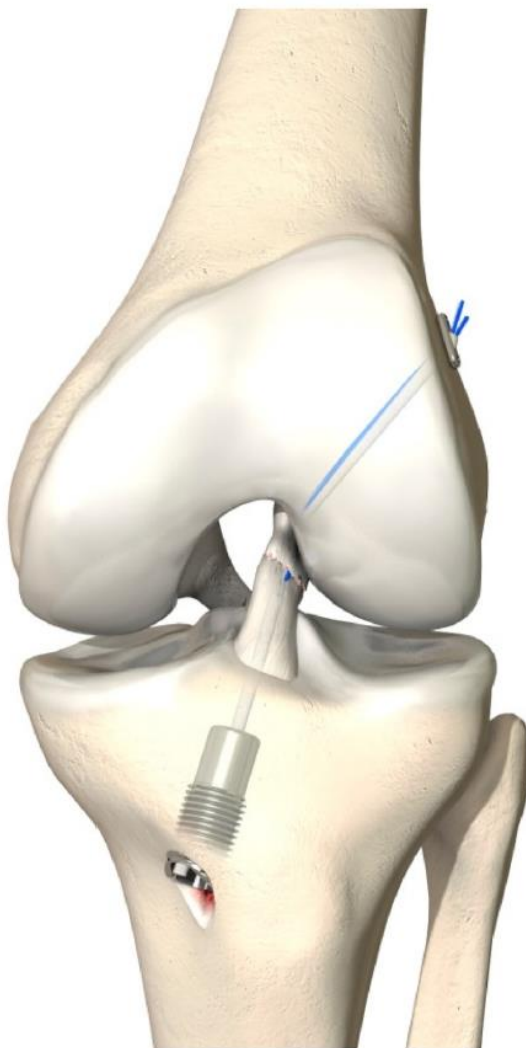


Figure 2

Work incapacity after accident. The area under the curve represents the total work incapacity over time. SE standard error.

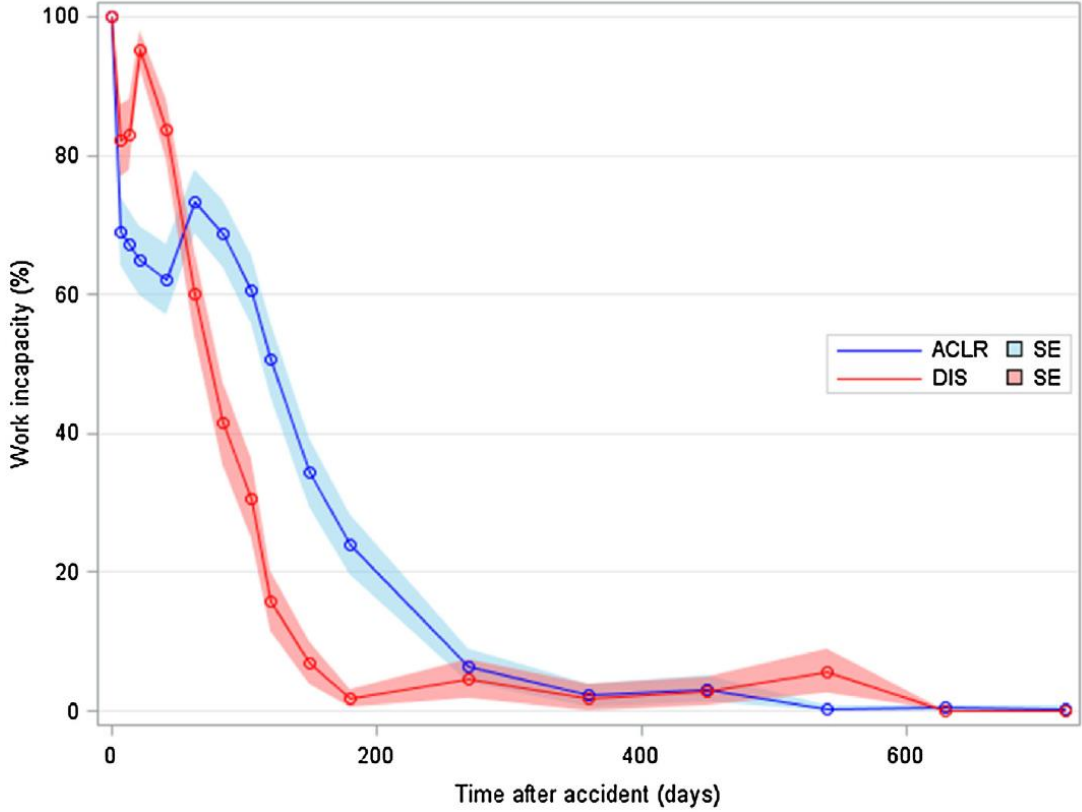


Figure 3

Work incapacity after surgery. The area under the curve represents the total work incapacity over time. SE standard error.

